



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/659,598

09/10/2003

Miri Seiberg

JBP-430-CIP1

5368

27777 7590 05/22/2009  
PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,598	<b>Applicant(s)</b> SEIBERG ET AL.	
	<b>Examiner</b> SHIRLEY V. GEMBEH	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 73-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 73-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/09 has been entered.
2. The response filed on **3/11/09** has been entered.
3. Applicant's argument filed on 9/12/08 has been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 73-86 are pending in this office action.

### ***Priority***

6. The present application, as to the claimed subject matter, "tretinoin", "non-denatured soybean " and "powder" is not described and therefore does not contain

Art Unit: 1618

priority back to parent 09/110,409 or 09/698,454. The disclosure of the prior-filed application, Application NOs. 09/110,409 & 09/698,454, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Thus, priority is granted to only the filing date, 09/10/03.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

7. Claims 73-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meybeck et al., (US 5,034,228) in view of Sessa et al. (1992) and Seiberg et al. J. (1997) is withdrawn and replaced with the rejection below.

8. The affidavit of KeShun Liu filed on 3/11/08 under 37 CFR 1.131 is insufficient to overcome the Meybeck et al. (US 5,034,228) reference. The argument that lecithin does not contain trypsin-inhibiting activity as supported by the declaration of KeShun Liu is reviewed, however Avramiotos et al teach that soy lecithin's contains trypsin inhibiting activity (see entire abstract) and therefore, not all lecithins are denatured.

Art Unit: 1618

9. Claims 73-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler et al (US 5,534,265) in view of Meybeck et al., US 5,034,228 as evidence by Sessa et al. (1986) and Seiberg et al. J. (1997) and Avramiotis et al (1996).

Fowler teaches a non-abrasive personal cleanser comprising synthetic soy flour that may be combined with other anti-acne agents useful for cleaning the skin (see col. 4, line 38 and col. 18, line 63; as required by instant claim 73 in part, 77-78, 80 and 84).

However Fowler fails to teach the composition is for treating acne and also fails to teach the non-denatured soy extract and tretinoin as required by instant claim 73. Even though Fowler fails to specifically teach that the soy flour is non-denatured, Fowler teaches that "the water –insoluble micronized particles of the present invention can be derived from a wide variety of materials" including natural sources which reasonably would be non-denatured (see col. 4, lines 18-40). Fowler also teaches retinoid as an anti-acne agent. As evidence by Sessa et al. *"Toasted Soybean Flour Components with Trypsin Inhibitor Activity"*, JAOCS, vol. 63, no. 6, June 1986, pp. 784-788, in which Fowler teaches that the source of the flour may be from both synthetic and natural sources. Therefore one of ordinary skill in the art would be motivated to substitute the synthetic soy flour of Fowler with Sessa's defatted soy flour or powder. Since Sessa teaches that soy flour comprises trypsin activity (see entire document) one of ordinary skill in the art would have substituted Fowler's synthetic soy flour with Sessa's natural flour and obtained non-denatured soybean extract.

Meybeck et al. teach treating acne with soya lecithin and tretinoin. It is known knowledge to one of ordinary skill in the art that soya lecithin is extracted from soybeans

Art Unit: 1618

or soybean powder and therefore the limitations of claims 73-74 and 76-78 are met. See col. 3, lines 36-38 and lines 61-64. With regard to claim 75, the Meybeck teaches tretinoin as vitamin A, (see col. 2, line 42). As to the soybean extract having trypsin inhibitory activity (see evidence by Avramiotis et al (1996)). Meybeck also teaches the formulation may comprise 2 g of soy lecithin and 0.1 g of tretinoin which is within the recited limitations of claims 79, 81-83 and 85-86 (see col. 3, line 62 of 0.01 to about 0.3% tretinoin and 0.01-50% of soybean extract).

However Meybeck fails to teach that the extracts are soy flour, soy paste and soymilk.

Based on the above teachings of Fowler, one of ordinary skill in the art would have substituted the synthetic soy flour with natural soy flour in the composition for rinsing skin which also contains an anti-acne agent that will intrinsically treat acne.

One of ordinary skill in the art would have been motivated to combine Fowler with Meybeck and substitute the synthetic soy flour of Fowler and the soy lecithin in Meybeck with the soy flour of Sessa because Sessa teaches that soy flour comprises trypsin inhibiting activity. One of ordinary skill in the art would routinely add water to the soy flour and form a paste. Therefore the use of soy flour is equivalent to using soy paste as required by instant claims 74. Since tretinoin is known in the art to be interchangeable with retinoid or vitamin A, one of ordinary skill in the art would have employed either tretinoin or vitamin A in a composition for treating acne since vitamin A is well known in the art for treating acne.

The adverse effect of vitamin A in the treatment of acne is that the skin is left dry and rough. Therefore it would have been obvious to one of ordinary skill in the art to treat acne with a retinoid compound such as tretinoin and retinol in combination with a soy product having trypsin inhibiting activity because, as evidenced by Seiberg et al., trypsin increases the therapeutic value of acne treatment and improves skin elasticity while reducing irritating effect. One of ordinary skill in the art would have been motivated to use a trypsin inhibitor such as a soy extract with either tretinoin or retinol because it is known in the art.

Applicant argues that lecithin does not contain trypsin-inhibiting activity as supported by the declaration of KeShun Liu (above), however Avramiotos teaches that soy lecithin's contains trypsin inhibiting activity (see entire abstract).

In response: There is controversy to whether soy lecithin extract contains trypsin-inhibiting activity. Note that claim 73 does not specify whether the soy bean extract is flour, paste or milk. Thus the claim limitation is met. Specifically Meybeck failed to teach whether soy lecithin is denatured or non-denatured. It is known that defatted soy lecithin's are denatured. Meybeck is silent to that. Therefore it is reasonably expected that lecithin is non-denatured because it is derived from a natural source. Under such circumstances, where the product seems to be identical, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). Based on the teaching of Avramiotos, lecithin does contain trypsin activity.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S.V.G./  
Examiner, Art Unit 1618  
5/15/09

/Robert C. Hayes/  
Primary Examiner, Art Unit 1649